

REMARKS

I. Status of the Claims

Claims 1-115 were originally filed. Claims 9, 10, 28-104, and 110 have been canceled. Claims 1-8, 11-27, 105-109, and 111-115 are currently under examination. Applicants note with appreciation that the Examiner has indicated the allowability of claims 1-4, 7, 8, 11-18, 20-27, 105-109, and 111-115.

II. Claim Rejections

A. Obviousness-Type of Double Patenting

The Examiner maintained the rejection of claims 5 and 19 under the judicially created doctrine of obviousness-type of double patenting, alleging that these two claims are unpatentable over claims 1-3 of U.S. Patent No. 6,592,877 ("the '877 patent"). Applicants respectfully traverse the rejection.

The subject matter of claims 1-3 of the '877 patent is an isolated fusion protein comprising four *M. tuberculosis* antigens: TbRa3 (SEQ ID NO:77), Tb38-1 (SEQ ID NO:88), TbH4 (SEQ ID NO:89), and 38kD (SEQ ID NO:155). In contrast, claim 5 of the present application is directed to a composition that contains a fusion protein comprising *M. tuberculosis* antigens MTb81 and Mo2, whereas claim 19 are directed to a composition that contains a fusion protein comprising at least two of *M. tuberculosis* antigens MTb81, Mo2, TbRa3, 38kD, Tb38-1 (MTb11), FL TbH4, HTCC#1 (Mtb40), TbH9, MTCC#2 (Mtb41), DPEP, DPPD, TbRa35, TbRa12, MTb59, MTb82, Erd14 (Mtb16), FL TbRa35 (Mtb32A), DPV (Mtb8.4), MSL (Mtb9.8), MTI (Mtb9.9A, also known as MTI-A), ESAT-6, α -crystalline, and 85 complex.

Because claim 5 relates to a fusion protein that comprises two *M. tuberculosis* antigens different from the four antigens named in claims 1-3 of the '877 patent, Applicants do not believe claim 5 is obvious in view of claims 1-3 of the '877 patent. Although at first glance claim 19 appears to refer to all four *M. tuberculosis* antigens named in claims 1-3 of the '877 patent, claim 19 in fact names an antigen ***FL TbH4*** instead of TbH4 (SEQ ID NO:89) in the

claims of the '877 patent. A close inspection of the actual amino acid sequences of FL TbH4 of the present application (which is SEQ ID NO:12, according to description on page 6 line 3 of the specification) and TbH4 of the '877 patent (which is SEQ ID NO:89) reveals that the two sequences are significantly different: SEQ ID NO:12 of the present application is a peptide of 286 amino acids and SEQ ID NO:89 of the '877 patent is a peptide of 166 amino acids (see Exhibit I). It is therefore clear that the fusion protein relevant to claim 19 is defined by a combination of *M. tuberculosis* antigens, not all of which are named in claims 1-3 of the '877 patent. Further, claim 19 does not explicitly name all four antigens recited in claims 1-3 of the '877 patent. Applicants therefore contend that the fusion protein of claim 19 is not obvious over claims 1-3 of the '877 patent.

As such, the withdrawal of the obviousness-type double patenting rejection is respectfully requested.

B. 35 U.S.C. §112, Second Paragraph

The Examiner rejected claim 6 under 35 U.S.C. §112, second paragraph, for its dependency from a rejected base claim. As discussed above, the only other outstanding rejection, the obviousness-type double patenting rejection, has been properly addressed. The rejection of claim 6 is therefore obviated.

PATENT

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

Respectfully submitted,

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Attachments (Exhibit I: SEQ ID NO:89 of U.S. Patent No. 6,048,910, as amended, in
present application)
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